K113673

AUG 3 2012

Section 5. 510(k) Summary

This 510(k) Summary has been submitted in accordance with the requirements of SMDA and 21 CFR §807.92 (c).

5.1.	**Submitter's Name :**	MedicalChain International Corp.
	Address :	No. 413, Ming-Hsouie Rd., Taipei, Taiwan
	Tel :	886-2-25322825
	Fax :	886-2-25636489
	Contact Person :	Ms. Lin Lee, Lee / President
	510 (k) Owner :	MedicalChain International Corp.
	Date Prepared :	Oct. 25, 2011
5.2.	**Device Name :**	*MySafety*® **Syringe for Insulin**
	Trade Name :	*MySafety*® **Syringe**
	(Proprietary Name)	
	Common Name :	Insulin Syringe (with attached needle)
	Classification Name :	Piston Syringe / Anti-Stick Syringe
	Classification :	Class II
	Regulatory Number :	21 CFR 880.5860
	Product Code :	FMF / MEG

5.3. Predicate Device :

MySafety® **Syringe K111734**

Disposable Insulin Syringe K110421

Product information of the predicate devices are provided in Appendix B1~B2.

5.4. Device Description :

The *MySafety*® **Syringe for Insulin** is a sterile, single-use, disposable, non-reusable, needle-retractable, piston syringe, provided with attached needle, which is intended for the injection of U-100 insulin into a diabetic patient, while minimizing the potential for accidental injury and preventing syringe reuse.

The *MySafety*® **Syringes for Insulin** will be available in different combinations of syringe capacities, needle gauges, and needle lengths.

5.5. Intended Use :

The *MySafety*® **Syringe for Insulin** is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe re-use and is a single use, disposable and retractable safety syringe which is intended for injection of insulin into the body.

5.6. Technological Characteristics

The *MySafety*® **Syringe for Insulin** has the same technological characteristics as the predicate devices.

5.7. Substantial Equivalence :

MedicalChain International Corp. makes a Substantial Equivalence claim of the *MySafety*® **Syringe for Insulin** to the predicate device # K110421, based on the similar needle / volume, specifications and same intended use.

MedicalChain International Corp. also makes a Substantial Equivalence claim of the *MySafety*® **Syringe for Insulin** to the predicate device K111734 based on the same design, technological characteristics, operational principles, materials and intended use as K111734. The only difference is the medication which the proposed device is intended to inject is insulin specifically, instead of the non-specified medical fluids of the predicate device K111734 .

5.8. Performance Summary :

The *MySafety*® **Syringe for Insulin** have been designed and successfully tested to meet the applicable requirements outlined in the FDA Recognized Consensus Standards, including ISO 6009, ISO 7864, ISO 7886-1, ISO 8537, ISO 9626, ISO 10993 series, ISO 11135-1, ISO 11607-1 and USP 33 : 2010 <151 > Pyrogen Test as listed in FORM FDA 3514 SECTION I – UTILIZATION OF STANDARDS on pages 2-5 ~ 2-6 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 3 2012

MedicalChain International Corporation
C/O Ms. Robin Hwang
Consultant
ICP Consulting Corporation
1808 Seabreeze Court
Thousand Oaks, California 91320

Re: K113673
Trade/Device Name: MySafety® Syringe for Insulin
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF,MEG
Dated: July 26, 2012
Received: July 31, 2012

Dear Ms. Hwang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Statement of Indications for Use

510(K) Number (if known):

Device Name : *MySafety*® Syringe for Insulin

Indications For Use:

The ***MySafety*® Syringe for Insulin** is designed as an anti-stick syringe to reduce the risk of sharps injuries and the potential for syringe re-use and is a single use, disposable and retractable safety syringe which is intended for injection of insulin into the body.

Prescription Use _____ AND / OR Over-The-Counter Use ___X___
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sijal Wu for RZC Aug 2, 2012
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113673